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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/668,876

09/22/2003

Michael Johnson

1975/US

3615

29693

7590

03/20/2008

WILEY REIN LLP
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EXAMINER

BERTRAM, ERIC D

ART UNIT

PAPER NUMBER

3766

MAIL DATE

DELIVERY MODE

03/20/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/668,876	Applicant(s) JOHNSON, MICHAEL	
	Examiner Eric D. Bertram	Art Unit 3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 November 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 15-17 and 19-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 15-17 and 19-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed 11/28/2007 have been fully considered but they are not persuasive. The applicant argues that Black does not disclose a portion of the overmold of the catheter remaining adjacent an exposed portion of an electrode. The Examiner respectfully disagrees. As described by Black, the lead is assembled using outer tubing 23, electrodes 18 and electrode spacers 28, as shown in figure 5. The completed assembly is then overmolded using an injection molding process that results in overmold material being forced into the area between the electrodes 18 and the inner stylet guide 24 (Col. 7, lines 12-18). Furthermore, this material is forced into any gaps or voids between insulative material (i.e., electrode spacer 28) and conductive material (i.e., electrode 18) (Col. 7, lines 29-33). This is due to the fact that Black states that the electrode spacers and terminal spacers are put into a state of flow in the overmolding process, and that after this overmolding process, the overmolded assembly is ground down to create an isodiametric lead (Col. 7, lines 12-15 and Col. 24-31). During grinding, Black discloses that overmolded material will be removed (Col. 7, line 25-29). Therefore, if no overmold material was forced into gaps between electrode spacer 28 and electrode 18, no overmold material would be present to be ground off. Therefore, when the overmolded assembly is grinded to create an isodiametric lead, the overmold material will still be present internally, as well as in any gaps between the electrode spacer and the electrodes that were filled. Both of these locations are considered to be "adjacent" (i.e., near or close) the exposed portion of the electrode. Furthermore, Black

discloses that the overmold material “partially surrounds” electrodes 18 (Col. 7, lines 16-17). The 35 USC 102(b) and 103(a) rejections of claims 15-17 and 19-33 are still considered proper.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 15, 17, 19-23, 25-27, and 29-33 are rejected under 35 U.S.C. 102(b) as being anticipated by Black et al. (US 6,216,045, hereinafter Black). Black discloses a catheter for use in a medical procedure, including a catheter body 22 and a catheter tip 34 operably connected to the catheter body. Black further discloses arbitrarily-shaped electrodes 18 attached to the catheter, wherein the electrodes, along with the entire catheter assembly is overmolded (Col. 7, lines 5-11). The overmolding is done using an injection molding process that results in overmold material being forced into the area between the electrodes 18 and the inner stylet guide 24 (Col. 7, lines 12-18).

Furthermore, this material is forced into any gaps or voids between insulative material (i.e., electrode spacer 28) and conductive material (i.e., electrode 18) (Col. 7, lines 29-33). Therefore, when the overmolded assembly is grinded to create an isodiametric lead, the overmold material will still be present internally, as well as in any gaps between the electrode spacer and the electrodes that were filled. Both of these locations are considered to be “adjacent” (i.e., near or close) the exposed portion of the

electrode. Finally, energy is delivered to the electrodes through wire conductors 20 (Col. 4, lines 3-17).

4. Regarding claims 17, 21-23, 25 and 26, Black discloses that the catheter body comprises a lumen tube 24 nested in jacket 23, wherein the wire conductors 20 are located on the exterior surface of the lumen tube (see figure 3). Black shows in figure 5 that the electrodes 18 must pass through the jacket 23 to contact the conductors.

5. Regarding claims 19 and 20, Black discloses that the electrodes are composed of biocompatible, conductive material, specifically platinum (Col. 3, lines 40-45).

6. Regarding claims 27, 29 and 30, it is the Examiner's position that the wire conductors are inherently traces, given its broadest reasonable interpretation.

7. Regarding claims 31 and 32, any gaps between electrode spacer 28 and electrode 18 helps insulate the electrodes from each other, and further contributes to a smooth finish by closing any voids.

8. Regarding claim 33, Black discloses that the overmold material "partially surrounds" electrodes 18 (Col. 7, lines 16-17).

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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10. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. Claim 16 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Black. Black, as described above, discloses the applicant's basic invention with the exception of electrodepositing the electrodes and traces onto the catheter.

However, it would have been an obvious matter of design choice to modify Black by electro-depositing the traces and electrodes onto the catheter since, upon reviewing the specification, the applicant has not disclosed that electro-depositing the traces and electrodes solves any stated problem or is for any particular purpose, and it appears that the catheter would perform equally well no matter how the electrodes or the traces have been attached to the catheter.

12. Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Black in view of Quackenbush (US 5,125,913). Black, as described above, discloses that applicant's basic invention, including a catheter comprising a tube along which wire is run. Black does not disclose, however, that the tube and wire are co-extruded.

Attention is directed to the secondary reference of Quackenbush, which discloses the use of co-extrusion when forming a medical catheter. Therefore, it would have been obvious to one of ordinary skill in that art at the time of the applicant's invention to

modify the catheter of Black by co-extruding the tube and wire as suggested by Quackenbush because co-extrusion is a cheaper process since two steps can be completed in a single step.

Conclusion

13. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric D. Bertram whose telephone number is 571-272-3446. The examiner can normally be reached on Monday-Friday from 9:30-6 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl H. Layno can be reached on 571-272-4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Carl H. Layno/
Supervisory Patent Examiner, Art Unit 3766

/E. D. B./
Examiner, Art Unit 3766